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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,835	05/19/2006	Joachim Arzt	06022	8773
24124 7590 04/09/2007 BOHAN, MATHERS & ASSOCIATES, LLC PO BOX 17707 PORTLAND, ME 04112-8707			EXAMINER UNDERDAHL, THANE E	
			ART UNIT	PAPER NUMBER
			1651	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/09/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/570,835

Applicant(s)

ARZT ET AL.

Examiner

Thane Underdahl

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5/10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/19/06.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21, 28-32, and 35-37 of copending Application No. 10/570920 in view of Brasile (U. S. Patent Application Publication # 2002/0012988). The co-pending claims are both drawn to a device for an extracorporeal storage of organs in an organ perfusion chamber. The difference between the copending claims is the use of an oxygenator in application 10/570,920 as opposed to application 10/570,835. However one of ordinary skill in the art would recognize that an oxygenator is an obvious addition to an extracorporeal organ storage device as taught by Brasile (page 4, paragraph 39) since growing animal tissue needs oxygen.

This is a provisional obviousness-type double patenting rejection.

***Claim Rejections - 35 USC § 112***

Claims 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 refers to two fluids: a vitality-preserving fluid and a storage fluid. It is unclear if these are two distinct fluids, are a mixture of fluids or the same fluid since as the claim is written the storage and vitality-preserving fluids are kept in the same perfusion chamber and ran through the same dialysis circuit. Also claim 5 includes the phrase "wherein said vitality-preserving fluid includes a dialysate circuit" is indefinite since it is unclear if it is the fluid that is ran through a dialysis circuit or the fluid is a dialysate. Clarification is required.

Claim 9 includes the phrase "comprises temperature-control loops embedded with a wall of said organ perfusion chamber". It is unclear if the temperature control device is providing another wall in the perfusion chamber or if the device is imbedded in the wall of the perfusion chamber. Clarification is required.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Brasile (U.S. Patent Application Publication # 2002/0012988).

These claims are drawn to a system for extracorporeal storage of organs comprising:

An organ perfusion chamber

A vitality-preserving liquid that is circulated into the organ perfusion chamber that includes circulation through a dialysis circuit.

A storage fluid that fills the perfusion chamber. The organ perfusion chamber serves as a reservoir for the storage fluid which is a dialysate and the storage fluid is added to the dialysis circuit from the reservoir as needed.

The system further comprises a temperature control device in the organ perfusion chamber to control the temperature of the storage fluid.

Brasile teach a system for the extracorporeal storage of organs that includes a perfusion chamber and a dialysis machine that circulates and purifies the vitality preserving storage liquid (Fig 1 and paragraph 23). The chamber includes a reservoir that replenishes the fluid circuit as it flows over the organ and is purified. The system includes a temperature control device to control the temperature of the vitality preserving storage fluid inside the perfusion chamber (page 2 paragraph 12).

Therefore the reference anticipates claims 5 and 6.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brasile as applied to claims 5 and 6 in the above rejection.

The description and rejection of claims 5 and 6 are listed in the 35 U.S.C § 102(b) rejection above.

Claim 8 limits the temperature control device is integrated into the wall of the organ perfusion chamber. Claim 9 limits that the temperature control device comprises temperature control loops embedded in the organ perfusion chamber.

Brasile teach an organ perfusion chamber with a heat exchanger and a temperature sensor situated within the organ perfusion chamber (page 7, paragraph 60). However Brasile does not specifically teach a temperature control device integrated into the wall of the organ perfusion chamber. However based on the disclosure by Brasile it would be prima facie obvious at the time of filing to modify the invention to integrate the temperature control device into the wall, since Brasile already places the temperature control sensors of the device in the perfusion chamber. Furthermore M.P.E.P. § 2144.04 B state that making a device integral "would be merely a matter of obvious engineering choice" and as such is prima facie obvious to make the temperature control device integral with the perfusion chamber.

Also since Brasile teach that the temperature controller maintains the temperature between 25-37 °C based on the input it receives from the sensor (page 7, paragraph 60) it is obvious that one of ordinary skill in the art would recognize that the system contains temperature control feedback loops.

Therefore the references listed above renders obvious claims 5, 6, 8, and 9.

Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brasile as applied to claims 5, 6, 8, and 9 in the above rejection.

The description and rejection of claims 5 and 6 are listed in the 35 U.S.C § 102(b) rejection above and the description and rejection of claims 8 and 9 are listed in the 35 U.S.C § 103(a) rejection above.

Claim 7 limits the temperature control device to a heating mat.

Brasile teach an organ perfusion chamber with a heat exchanger and a temperature sensor situated within the organ perfusion chamber (page 7, paragraph 60). Brasile does not teach that the heat exchanger is a heating mat. However it would have been obvious to someone skilled in the art at the time the invention was made that multiple methods can be used to heat the storage solution included a water heater to circulate warmed water around the reservoir (page 7, paragraph 60). One of ordinary skill in the art would recognize that a heat exchanger can include heating elements as well as a heating mat since both are known in the art to heat liquid as taught by Cooksley et al. (col 2, lines 65-70). Therefore it would be *prima facie* obvious to use a heating mat as a heat exchanger for the perfusion chamber. The references above render obvious claims 5-9.

Claims 5,6, and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brasile as applied to claims 5, 6, 8, and 9 above, and further in view of Bacchi et al. (U. S. Patent # 5,285,657, 1994).

The description and rejection of claims 5, 6, 8, and 9 are listed in the 35 U.S.C § 103(a) rejection above by Brasile et al. Claim 10 further limits that the organ perfusion chamber is hermetically sealed against fluid and pressure.

While Brasile does teach an organ perfusion chamber in combination with a temperature control device and dialysis system he does not specifically teach that the organ perfusion chamber is hermetically sealed against fluid and pressure. He does teach that it is important to minimize perfusion contamination due to contact with air (Brasile, page 9 paragraph 78) which provides motivation to hermetically (airtight) seal the chamber. However it would have been obvious to someone skilled in the art at the time the invention was made to make the organ perfusion chamber hermitically sealed in view of Bacchi et al. who teach an insulated organ perfusion chamber (Bacchi, col 1, lines 45-50) for extracorporeal organ transport (Bacchi, see abstract). Bacchi et al. teach that the lid of this chamber is hermetically sealed (col 7, line 45-50).

It would have been obvious to someone skilled in the art to modify the invention of Brasile with the hermetically sealed lid taught by Bacchi et al. The motivation is provided by Brasile who desires minimal contact with air and the organ. Bacchi et al. provides the reasonable expectation of success by making an organ perfusion chamber that is hermetically sealed.

Furthermore, M.P.E.P. § 2144.06 holds that it is obvious that since both devices are known for the same purpose (extracorporeal organ storage) it would be obvious to combine the elements of both devices to form a their device used for the same purpose.



Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 5,6, and 8-10 are not allowable.

In summary no claims, as written, are allowed for this application.

**In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure**, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

#### CONTACT INFORMATION

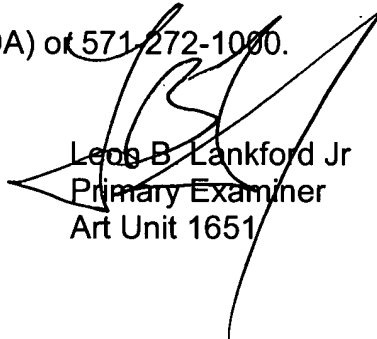
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached during regular business hours, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1651



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